REMARKS

Introductory Comments:

Claims 26, 27 and 30-45 were examined in the Office Action under reply and stand rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,334,856 to Allen et al. ("Allen"); U.S. Patent No. 6,743,211 to Prausnitz et al. ("Prausnitz"); and U.S. Patent No. 6,656,147 to Gertsek et al. ("Gertsek"). These rejections are believed to be overcome as discussed more fully below.

Overview of the Above Amendments:

Claims 26, 30 and 39 have been amended to recite the subject invention with greater particularity. Specifically, claims 26, 30 and 39 have been amended to recite that the micro-perforators are formed of a "solid" dissolvable matrix. Claims 26, 30 and 39 have also been amended to recite that the matrix material forms channels for delivering a substance by "diffusion" when dissolved. Finally, claims 26, 30 and 39 now recite that the matrix material dissolves "over a time interval of between a few tens of seconds and a few hours."

Support for the amendments can be found in the original claims, as well as throughout the specification at e.g., page 3, lines 23-24; page 4, lines 1-3; page 5, lines 17-18; and page 13, lines 22-26.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the unamended claims.

Rejections Over the Art:

Claims 26, 27 and 30-44 were rejected under 35 U.S.C. §102(e) as anticipated by Allen. Claims 26, 27 and 30-45 were rejected under 35 U.S.C. §102(e) as anticipated by Prausnitz. Finally, claims 26, 27, 30-32, 34 and 38 were anticipated under 35 U.S.C. §102(e) as anticipated by Gertsek. The Examiner contends that each of these references "discloses an array of dissolvable microperforators and a reservoir patch with a solvent." Office Action, page 2. However, none of

these references is believed to anticipate the present claims.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

None of Allen, Prausnitz or Gertsek teaches or suggests an array of micro-perforators with a **solid dissolvable matrix** as claimed. Neither do these references describe the formation of channels for delivering a substance by diffusion, also as claimed. As explained throughout the present application, the salient feature of applicant's invention is that the perforators used to pierce or otherwise make diffusion channels in the skin are **themselves dissolvable**. The solid matrix that forms the perforators can be made of the drug to be delivered and/or of a soluble material that quickly dissolves after insertion into the skin. This technology is quite distinct from hollow needle technologies and the like, that use microneedles and other injection devices made from materials such as metals and polymers that do not dissolve rapidly upon contact with the skin.

For example, Allen uses porous or hollow microneedles that are inserted into skin. As explained at column 3, lines 20-28, and columns 4-5, bridging paragraph of Allen, the microneedle acts as a conduit through which fluid flows into the skin. Allen's microneedle includes valves, pumps, electrical means and the like, for delivering the fluid through a microneedle conduit, in contrast to applicant's system that uses diffusion through channels formed by the dissolution of the solid matrix of the micro-perforators. Although Allen states that his microneedles can be made from biodegradable polymers, the biodegradable polymers described do not dissolve within seconds or hours as claimed. It is well known in the art that biodegradable polymers take much longer to degrade. Indeed, Allen states that the microneedles should remain intact for a number of days.

Prausnitz, like Allen describes hollow microneedles. Prausnitz mentions in passing that the microneedles can be "biodegradable" but, as explained above, such materials do not dissolve rapidly

as claimed. Moreover, there is no disclosure regarding the formation of channels due to the dissolution of the microneedles, through which the substance to be delivered diffuses.

Gertsek also fails to describe the claimed invention. As explained at column 5, lines 33-36 of Gertsek, the microneedles are made from metals, glass polymers and other non-reactive metals and alloys. There is no disclosure regarding the use of solid dissolvable matrices. The passage at column 8, lines 37-46, cited by the Examiner, explains that a bladder present can contain either a drug or diluent to dissolve a dried drug in the cavity or on the surface of the microneedles. Thus, contrary to the present invention, this embodiment uses needles that are coated with the desired substance. Thus, none of the cited art teaches each and every element of the claimed invention and therefore cannot anticipate the present claims.

CONCLUSION

Applicant respectfully submits that the present claims are patentable. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated. If the Examiner notes any further matters which she believes may be expedited by a telephone interview, she is requested to contact the undersigned attorney at (650) 493-3400.

Respectfully submitted,

Date: 2/10/06

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